(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter for use of 250 milligram tablets; see No. 000856 in § 510.600(c) of this chapter for use of 50 and 250 milligram tablets.

(c) *Conditions of use in dogs*—(1) *Amount*. Twenty-five milligrams of primidone per pound of body weight (55 milligrams per kilogram of body weight) daily.[1]

(2) *Indications for use*. For the control of convulsions associated with idiopathic epilepsy, epileptiform convulsions, viral encephalitis, distemper, and hardpad disease that occurs as a clinically recognizable lesion in certain entities in dogs.[1]

(3) *Limitations*. The tablets may be administered whole or crushed and mixed with the food. When convulsions are frequent, the dosage should be divided and administered at intervals. Reduction in dosage should be made gradually and never be abruptly discontinued. Do not use in feline species, as primidone appears to have a specific neurotoxicity in cats. Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[42 FR 61594, Dec. 6, 1977, as amended at 43 FR 55386, Nov 28, 1978; 46 FR 8467, Jan. 27, 1981; 46 FR 57477, Nov. 24, 1981; 53 FR 40727, Oct. 18, 1988; 56 FR 37473, Aug. 7, 1991; 62 FR 35076, June 30, 1997]

§ 520.1920 Prochlorperazine, isopropamide sustained release capsules.

(a) *Specifications*. Prochlorperazine, isopropamide sustained release capsules contain either:

(1) 3.33 milligrams of prochlorperazine (as the dimaleate) and 1.67 milligrams of isopropamide (as the iodide), or

(2) 10 milligrams of prochlorperazine (as the dimaleate) and 5 milligrams of isopropamide (as the iodide).

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used for the treatment of dogs in which gastrointestinal disturbances are associated with emotional stress.

(2)(i) Capsules described in paragraph (a)(1) of this section are administered orally to dogs weighing from 4 to 15 pounds at the rate of 1 capsule twice daily. These capsules are administered orally to dogs weighing from 16 to 30 pounds at the rate of 1 or 2 capsules twice daily. For dogs weighing less than 4 pounds, administer orally an appropriate fraction of the contents of one of these capsules.

(ii) Capsules described in paragraph (a)(2) of this section are given to dogs weighing 30 pounds and over at the rate of 1 capsule twice daily.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1921 Prochlorperazine, isopropamide, with neomycin sustained-release capsules.

(a) *Specifications*. Each capsule contains either:

(1) Capsule No. 1: 3.33 milligrams of prochlorperazine (as the dimaleate), 1.67 milligrams of isopropamide (as the iodide), and 25 milligrams of neomycin base (as the sulfate); or

(2) Capsule No. 3: 10 milligrams of prochlorperazine (as the dimaleate), 5 milligrams of isopropamide (as the iodide), and 75 milligrams of neomycin base (as the sulfate).

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer capsules orally twice daily to dogs as follows:

Animal weight (pounds)	Number of capsules per dose	
	Capsule No. 1	Capsule No. 3
10 to 20	1	
20 to 30	2	
Over 30	3	1
Over 60		2

(2) *Indications for use*. For treatment of dogs in which infectious bacterial gastroenteritis is associated with emotional stress.

(3) *Limitations*. Do not continue medication longer than 5 days. Overdosage or prolonged administration may

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

produce nephrotoxicity as manifested by albuminuria, presence of granular casts and depressed urinary output. If it is desirable to administer a vasoconstrictor, norepinephrine is the drug of choice. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 14103, Apr. 10, 1984, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1962 Promazine hydrochloride.

(a)(1) *Chemical name.* 10-[3-(Dimethylamino)propyl]phenothiazine monohydrochloride.

(2) *Specifications.* Conforms to N.F. XII.

(3) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(4) [Reserved]

(5) *Conditions of use.* (i) The drug is used for quieting excitable, unruly, or intractable horses. It is administered at a dosage level of 0.45 to 0.9 milligrams of promazine hydrochloride per pound of body weight mixed with an amount of feed that will be readily consumed.

(ii) Do not use in horses intended for food.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) [Reserved]

[40 FR 13838, Mar. 27, 1975, as amended at 43 FR 55386, Nov. 28, 1978; 59 FR 5705, Feb. 8, 1994]

§ 520.2002 Propiopromazine hydrochloride.

(a) *Chemical name.* 1-Propanone, 1-[10-[3-(dimethylamino) propyl] phenothiazine-2-yl]-, monohydrochloride.

(b) *Specifications.* The drug is administered in a chewable tablet containing 10 to 20 milligrams of propiopromazine hydrochloride.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is intended for oral administration to dogs as a tranquilizer. It is used as an aid in handling difficult, excited, and unruly dogs, and in controlling excessive kennel barking, car sickness, and severe dermatitis. It is also indicated for use in minor surgery and prior to routine examinations, laboratory procedures, and diagnostic procedures.

(2) It is administered at the rate of 0.5 to 2 milligrams of propiopromazine hydrochloride per pound of body weight once or twice daily depending upon the degree of tranquilization desired.

NOTE: Not for use with organophosphates and/or procaine hydrochloride, as phenothiazine may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride. Overdosage may produce significant depression.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 60570, Dec. 11, 1981; 61 FR 5506, Feb. 13, 1996]

§ 520.2041 Pyrantel pamoate chewable tablets.

(a) *Specifications.* Each tablet contains pyrantel pamoate equivalent to 22.7 or 113.5 milligrams pyrantel base.

(b) *Sponsor.* See Nos. 017135 and 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Provides at least 2.27 milligrams pyrantel base per pound body weight for dogs weighing more than 5 pounds, and at least 4.54 milligrams of pyrantel base per pound body weight for dogs weighing 5 pounds or less.

(2) *Indications for use*—(i) *In dogs and puppies.* For removal of ascarids (*Toxocara canis; Toxascaris leonina*) and hookworms (*Ancylostoma caninum; Uncinaria stenocephala*).

(ii) In puppies and adult dogs and in lactating bitches after whelping. To prevent reinfection of *Toxocara canis.*

(3) *Limitations.* Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Retreatment of adult dogs may be necessary at monthly intervals as determined by laboratory fecal examinations. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[52 FR 37937, Oct. 13, 1987, as amended at 57 FR 48163, Oct. 22, 1992; 58 FR 44611, Aug. 24, 1993; 66 FR 9650, Feb. 9, 2001; 67 FR 21996, May 2, 2002]

§ 520.2042 Pyrantel pamoate tablets.

(a) *Specifications.* Each tablet contains pyrantel pamoate equivalent to